510(k) SUMMARY
Caremed Supply
Vesoflow SQS and IPCS
Deep Vein Thrombosis Device

AUG 25 2011

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared:

Caremed Supply, Inc.
C/O Spectre Solutions, Inc.
5905 Fawn Lane
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Contact Person:
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Caremed Supply, Inc.
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Date Prepared: February 2, 2011

Name of Device and Name/Address of Sponsor:

Caremed Supply, Inc.
7f, no.2, lane 235, bao chiao
rd, xin tien city
taipei xen, China 231
Phone: 886-2-29179808
Fax: 886-2-29186505

Common or Usual Name:

Compression Therapy Device

Classification Name

Sleeve, Limb, Compression

Predicate Devices

Huntleigh Healthcare Universal Flowtron (K010744)
Tyco/Kendall SCD Express (K040511)

K110977
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Indication for Use:

The Caremed Supply Inc. Vesoflow SQS and IPCS Deep Vein Thrombosis (DVT) Compression Devices are intended to increase venous blood flow in at risk patients in order to help prevent deep vein thrombosis.

Technological Characteristics and Substantial Equivalence

A. **Device Description**

The Caremed Vesoflow® SQS and IPCS Deep Vein Thrombosis (DVT) Compression Systems are electrically powered, non-invasive mechanical compression devices designed for use by patients for whom external compression therapy is indicated. Their intended function and use is to increase venous blood flow and help prevent Deep Vein Thrombosis (DVT), by applying intermittent, controlled pressure to the calf, thigh or foot.

The Vesoflow product will be available in two (2) models. These are the Vesoflow SQS and the Vesoflow IPCS. They differ in that the SQS delivers sequential compression therapy while the Vesoflow IPCS delivers intermittent compression therapy.

B. Substantial Equivalence

Products which are substantially equivalent to the Vesoflow are the Tyco/Kendall SCD Express ***(K040511)*** and the Huntleigh Healthcare Flowtron Universal ***(K010744).***

Performance Data

The Vesoflow SQS and IPCS compression therapy devices have been tested to and meet IEC 60601-1 Standard for Medical electrical equipment, Part 1: General requirements for safety. Garments were tested internally by Caremed and met their specified requirements.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Caremed Supply, Inc.
c/o Mr. Edward A. Kroll
President Spectre Solutions, Inc.
7F, No. 2, Lane 235
Baoqiao Road
Xindian City 231
Taipei 231, Taiwan China

AUG 25 2011

Re: K110977
Vesoflow® SQS and IPCS Deep Vein Thrombosis (DVT) Compression Therapy System (Vesoflow®)
Regulation Number: 21 CFR 870.5800
Regulation Name: Compressible Limb Sleeve
Regulatory Class: Class II
Product Code: JOW
Dated: July 23, 2011
Received: July 27, 2011

Dear Mr. Kroll:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K110977

Indications for Use

510(k) Number (if known): TBD

Device Name: Vesoflow SQS and IPCS Deep Vein Thrombosis (DVT) Compression System

Indications for Use:

The Caremed Supply Inc. Vesoflow SQS and IPCS Deep Vein Thrombosis (DVT) Compression Devices are intended to increase venous blood flow in at risk patients in order to help prevent deep vein thrombosis.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K110977